UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SEKISUI AMERICA CORPORATION and SEKISUI MEDICAL CO. LTD., Plaintiffs, v. RICHARD HART and MARIE LOUISE TRUDEL-HART, Defendants.	12 Civ. 3479 (SAS)

REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS

SULLIVAN & WORCESTER LLP
Franklin B. Velie
Jonathan G. Kortmansky
Siobhan Briley
1633 Broadway, 32nd Floor
New York, New York 10019
Telephone: (212) 660-3000
Facsimile: (212) 660-3001

Attorneys for Defendants
Richard Hart and Marie Louise Trudel-Hart

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Louise Marie Trudel-Hart ("Ms. Trudel-Hart") and Richard Hart ("Mr. Hart") (together, the "Harts") respectfully submit this reply memorandum of law in further support of their motion to dismiss Plaintiffs' Complaint for failure to state a claim for relief, pursuant to Federal Rule of Civil Procedure 12(b)(6).

INTRODUCTION

Plaintiffs' opposition fails to remedy the defects of their Complaint. Plaintiffs' fraud claim is based on allegations that the Harts misrepresented the likelihood that the FDA would approve in 2009 the March 15, 2009 FEMTELLE 510(k) submission, submitted 10 days after the execution of the stock purchase agreement ("SPA"). Plaintiffs argue that the misrepresentations they relied on were made in a confidential memorandum delivered to them in October 2008. Plaintiffs' argument is without merit. First, the SPA contains no representations regarding the March 15, 2009 submission. Second, Section 4.29 of the SPA is dispositive of Plaintiffs' fraud claim as it contains an express disclaimer of all pre-SPA statements. Third, Plaintiffs' claim ignores the express disclaimers in the confidential memorandum. Finally, Plaintiffs' opposition fails to demonstrate that the Complaint satisfies the heightened pleading standard for fraud.

Plaintiffs' breach of contract claim fails to meet the pleading requirements of *Iqbal* and *Twombly* because it alleges no facts showing that the problems complained of existed on or before April 20, 2009 (the "Closing Date" or "Closing"), *i.e.*, the date the representations and warranties were made. In response, rather than pointing to allegations that make the requisite showing, Plaintiffs argue that the Court must infer when the alleged problems arose. The Complaint alleges no facts to support this inference.

ARGUMENT

I. Plaintiffs' Fraud Claim Fails.

A. Plaintiffs Plead No Misrepresentation or Omission on Which They Relied.

The Harts previously demonstrated that Plaintiffs' fraud claim fails because the statements regarding FEMTELLE (a product in ADI's pipeline) on which they claim reliance are not actionable because (1) they are statements of opinion regarding the future approval of FEMTELLE by the FDA, and (2) they are financial projections assuming FDA approval is obtained. *See Int'l Fin. Corp. v. Carrera Holdings Inc.*, 82 A.D.3d 641, 642, 920 N.Y.S.2d 310, 311 (1st Dep't 2011) ("expressions of hope and opinion, and related to future expectations," are not actionable as fraud); *Rombach v. Chang*, 355 F.3d 164, 174 (2d Cir. 2004) ("expressions of . . . corporate optimism do not give rise to" fraud). The Harts further showed that regardless of whether the statements are actionable, Section 4.29 of the SPA contains an express disclaimer of those very statements.

To stave off dismissal, Plaintiffs argue that two allegations plead misrepresentations on which they justifiably relied. Opp. at 18. The first is that "Defendants falsely represented that FEMTELLE 510(k) clearance was expected by the fourth quarter of 2009 when in fact there was no reasonable expectation that FEMTELLE would ever receive 510(k) clearance based on the 2009 510(k) submission." Compl. ¶ 55(a). The second is that the Harts told Plaintiffs that "the ADI Group has conducted a number of discussions with the U.S. FDA and submitted an application for 510(k) clearance which the Company expects to receive by the fourth quarter of FY 2009." (Compl. ¶14). Neither of these allegations saves Plaintiffs' fraud claim.

The 2009 510(k) submission was made on March 15, 2009, *i.e.*, 10 days after the SPA

was executed. Compl. ¶¶23, 32. The SPA contains no representations and warranties about the likelihood of approval of the 2009 submission. Nor do Plaintiffs allege any. In fact, the SPA does not require that the Harts make any submission. SPA § 6.1 (last paragraph). Instead, the statements and projections on which Plaintiffs claim reliance were made in a confidential memorandum prepared by Crosstree Capital Partners, ADI's advisory company, dated August 2008 and provided to Plaintiffs in October 2008 (the "Confidential Memorandum" or "CM"). Compl. ¶¶ 12-15, 21-22, 55-58. As the Harts showed in their moving papers, these, and all other pre-SPA statements, were expressly disclaimed in Section 4.29 of the SPA and cannot form the basis for a fraud claim. Section 4.29, entitled "Disclaimer of Other Representations and Warranties," provides:

> Except as otherwise expressly set forth in this Article IV (including the Schedules attached hereto), neither the Principal Shareholders nor the Company makes any representation or warranty, express or implied, at law or in equity, in respect of the Company or any of its assets, liabilities or operations. The representations and warranties in this Article IV supersede and replace all prior statements, representations, projections, forecasts, warranties and other understandings (whether written or oral) that may have been previously given or made by the Principal Shareholders or the Company that may have related in any way to the subject matter of this Agreement ***including the projections set forth in the Confidential Memorandum***[.]" SPA § 4.29 (emphasis added).

Plaintiffs defend that Section 4.29 does not disclaim their reliance because there are no affirmative statements or promises by them in that section. Opp. at 19. This argument fails. When an agreement contains an express disclaimer of the statements on which reliance is pled, reliance is not justified as a matter of law. *Koch v. Greenberg*, No. 07 Civ. 9600 (BSJ)(DF), 2008 WL 4450273, at *3 (S.D.N.Y. Sept. 30, 2008) ("a party cannot justifiably rely on a representation that has been *explicitly* disclaimed in the agreement") (emphasis in original).

In any event, the Confidential Memorandum itself contains several disclaimers

precluding reliance on the statements within it.[1] On the cover page, it states, "This Confidential Memorandum does not constitute an offer to sell or the solicitation of an offer to purchase the Company's securities, and it should not and may not be relied upon in connection therewith." CM, cover page. This disclaimer is repeated on page 4, which adds, "interested parties must conduct their own independent, in-depth investigation and analysis of the Company and the information set forth in this Confidential Memorandum and any other written or oral communication transmitted or made available to" them. *Id.* at 4. Page 5 of the Confidential Memorandum is entitled "Confidentiality and Disclaimer." It states in relevant part:

> Only those particular representations and warranties which may be made by the Company in a definitive written agreement, when and if one is executed, shall have any legal effect. By its acceptance of this Confidential Memorandum, the recipient acknowledges the responsibility to perform a due diligence review at its own cost prior to any investment in or transaction with the Company.
>
> . . . This Confidential Memorandum also includes certain statements, estimates, projections . . ., and certain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such statements, estimates, information and projections reflect significant assumptions and subjective judgments by the Company's management concerning anticipated results. Such statements are subject to certain risks and uncertainties. The Company cautions suitors not to place undue reliance on forward-looking statements, which speak only as to management's expectations on the data herein. These assumptions and judgments may or may not be correct and there can be no assurance that any projected results are attainable or will be realized. . . . [N]either the Company nor Crosstree makes any representations or warranties as to their accuracy or completeness. CM at 5.

[1] Plaintiffs specifically refer to and quote from the Confidential Memorandum in the Complaint (*see* Compl. ¶¶ 13-15, 55-58) but do not attach it. Where "a plaintiff chooses not to attach to the complaint . . . a [document] upon which it solely relies and which is integral to the complaint, the defendant may produce the [document] when attacking the complaint for failure to state a claim, because plaintiff should not so easily be allowed to escape the consequences of its own failure." *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47 (2d Cir. 1991). The Confidential Memorandum is attached as Exhibit A to the Kortmansky Declaration ("Kortmansky Dec."). As set forth in paragraph 2 of the Kortmansky Dec., counsel for the Harts was able to obtain a copy of the Confidential Memorandum on August 9, 2012.

In light of these extensive disclaimers, which Plaintiffs must have been aware of when they filed their Complaint and opposition papers, "reliance on the [alleged statements is] unreasonable as a matter of law." *Kosovich v. Metro Homes, LLC*, No. 09 Civ. 6992 (JSR), 2009 WL 5171737, at *3 (S.D.N.Y. Dec. 30, 2009) (express disclaimers in brochure advertising investment opportunity defeated plaintiff's fraud claim); *see also Mid-Atl. Residential Investors Ltd. P'ship v. McGuire*, 166 A.D.2d 205, 560 N.Y.S.2d 431, 433 (1st Dep't 1990) (reliance on statements that are "contrary to the specific disclaimers recited in" an agreement is barred).

B. Plaintiffs Fail to Meet the Heightened Pleading Standards for Fraud.

The Harts showed that the Complaint alleges no facts that "detail the statements (or omissions) that the plaintiff contends are fraudulent, [] identify the speaker, [] state[] where and when the statements (or omissions) were made, [or] explain why the statements (or omissions) are fraudulent." *Landesbank Baden-Wurrtemberg v. Goldman, Sachs & Co.*, No. 11-4443, 2012 WL 1352590, at *1 (2d Cir. Apr. 19, 2012). Plaintiffs respond that the allegations in paragraphs 21-22, 33 and 56 of the Complaint suffice. Opp. at 20. Plaintiffs are wrong.

Paragraph 21 pleads that "ADI's primary contact with the FDA was ordered by Hart to 'stay away' from KPMG during the due diligence period"[2] and paragraph 22 alleges that without access to material information KPMG, the firm conducting due diligence, was not able to fully analyze the financial data. Compl. ¶¶ 21-22. These allegations concern Plaintiffs' due diligence rights, and have nothing to do with their fraud claim. Dismissal of a fraud claim is required

[2] In Plaintiffs' Answer and Counterclaims in No. 12 Civ. 3560, filed on July 9, 2012, Plaintiffs duplicated the claims made in this action. *See* Dkt. No. 9. The Court may take judicial notice of the Answer and Counterclaims. *Rothman v. Gregor*, 220 F.3d 81, 92 (2d Cir. 2000). Substantially all of Plaintiffs' Counterclaims are verbatim recitals of their allegations here. *Cf.* Dkt. No. 9, ¶¶ 45-93. The allegation in paragraph 21, however, was modified to plead, "ADI's primary contact with the FDA was never made available to KPMG during the due diligence period." Answer and Counterclaims ¶ 55. The revision eliminates any allegation of wrongdoing.

where that claim is asserted alongside breach of contract and is not based on matters collateral to the contract. *Telecom Intl'l Am., Ltd. v. AT&T Corp.*, 280 F.3d 175, 196 (2d Cir. 2001).

Paragraphs 33 and 56 concern the statement of opinion in the Confidential Memorandum that "the Company expect[ed] to receive [FEMTELLE 510(k) clearance] … by the fourth quarter of FY 2009." Compl. ¶ 14. Plaintiffs concede these are statements of opinion, but cite two cases to argue that they are actionable. Opp. at 18. Plaintiffs are wrong.

In both cases cited by Plaintiffs, the court held that the defendants misrepresented *existing* facts to support a contemporaneous opinion. *See Cohen v. Koenig*, 25 F.3d 1168, 1172 (2d Cir. 1994) (defendants' financial projections "foster[ed] a mistaken belief concerning a material fact"); *Cristallina S.A. v. Christie, Manson & Wood Int'l, Inc.*, 117 A.D.2d 284, 294, 502 N.Y.S.2d 165, 172 (1st Dep't 1986) (defendant's selection of paintings that "would be difficult, if not impossible, to sell and the dissemination of estimates at variance with the reserves and his earlier predictions, raise serious questions as to whether [defendant] misrepresented the prices which could be obtained at public auction"). Here, Plaintiffs do not and cannot plead that the Harts made any statements at all, opinion or otherwise, about the possible future success of the 2009 510(k) submission.[3]

Finally, Plaintiffs failed to plead intent. In opposition, Plaintiffs do not point to a single allegation that pleads intent. Instead, they argue that intent can be pled generally. Opp. at 20. Pleading "generally" does not permit pleading nothing, as Plaintiffs do. Plaintiffs' claim fails.

[3] The only allegation even relevant to the issue is that, "[u]nbeknownst to Plaintiffs, however, and well known to Defendants, the FEMTELLE 510(k) had little chance of success." Compl. ¶ 33. This conclusory allegation fails to even plead a *fact*, much less the Harts' misrepresentation as to an existing fact.

II. Plaintiffs' Claim for Breach of the Representations and Warranties in the SPA Fails.

Plaintiffs have not pointed to a single allegation in the Complaint from which the Court can reasonably infer that the alleged breaches, purportedly discovered a year after the Closing Date, arose before the Closing Date. The only allegation Plaintiffs cite—paragraph 42, which states, "numerous breaches in Defendants' representations and warranties existed at the time of SAC's purchase," Opp. at 13—is purely conclusory. It merely restates Plaintiffs' legal conclusion that the Harts breached the SPA. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("Threadbare recitals of the elements of a cause of action … do not suffice."); *id.* at 678-79 ("Rule 8 … does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions.").

Plaintiffs do not address the Harts' exemplar demonstrations (regarding paragraphs 42(c), (d) and (*l*)) that the Complaint contains no facts to establish that the problems identified existed before the Closing Date. Conceding this pleading defect, Plaintiffs argue that "it must be reasonably inferred, based on Sekisui's discovery of these extensive violations that were deeply entrenched in the company's operations within days after Hart and his head of manufacturing stopped running the company [in March/April 2010 (Compl. ¶¶36-39)], that [the alleged] conditions existed long before Sekisui's acquisition of ADI." Opp. at 13. No such inference, however, can be drawn.

Mr. Hart's employment with ADI following the Plaintiffs' acquisition is immaterial to the issue of when the problems first arose. In any event, the SPA states that Plaintiffs took "sole and exclusive control and discretion over the direction and operation of" ADI on the Closing Date. SPA § 2.6(d).

In addition, Plaintiffs baldly assert that each of the alleged problems establishes a breach. Opp. at 15. None does. Paragraphs 42(d), (e), (g), (h) and (j) allege problems with ADI "products" but identify no specific product(s). Paragraphs 42(d), (g), (h), (j), (*l*), (m) and (n) do not tie the problems alleged to any representation or warranty. *See Fuji Photo Film U.S.A., Inc. v. McNulty*, 669 F. Supp. 2d 405, 416 (S.D.N.Y. 2009) (Scheindlin, J.) (plaintiff "must allege the specific provisions of the contract upon which the breach of contract claim is based"). All but two (¶¶ 42(e), (g)) lack any temporal component at all, let alone one sufficient to establish that the complained of problems existed before the Closing Date. *See Boart Longyear Ltd. v. Alliance Indus., Inc.*, No. 12 Civ. 1346, 2012 WL 2357197, at *5 (S.D.N.Y. June 20, 2012) (Scheindlin, J.) (failure "to sufficiently plead facts plausibly indicating that the former employees were solicited *while* they were still employees" fatal to claim of breach). Another, Paragraph 42(h), is contradicted by the SPA. *See* SPA Sched. 4.14(c) (attached as Exhibit B to the Kortmansky Dec.) (Product 826 registered with "K Number" K052124).[4] Paragraphs 42(a), (b), (c), (e), (f), (i), (j) and (k) are legal conclusions that must be disregarded. *See Iqbal*, 556 U.S. at 678 ("tenet that a court must accept as true all of the allegations contained in the complaint is inapplicable to legal conclusions").

Plaintiffs try to salvage their breach claim by highlighting two allegations. Opp. at 5. Plaintiffs allege that certain machines, known as lyophilizers, were not properly validated. Compl. ¶ 42(b). Plaintiffs allege no facts to suggest that this condition existed before the Closing Date. Plaintiffs now argue that it must have been the Harts' fault unless Plaintiffs

[4] The validity of this registration can be confirmed on the FDA's website, at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=19105 (last accessed Aug. 22, 2012). The Court may take judicial notice of the validity of the registration. *See Magnoni v. Smith & Laquercia, LLP*, 701 F. Supp. 2d 497, 501 (S.D.N.Y. 2010) (judicial notice of "Web sites published on the internet" appropriate).

invalidated the machines. This does not follow. For all that appears, Plaintiffs just failed to keep the authorizations current. Second, Plaintiffs conclude that ADI's failure to maintain design files "necessarily existed before SAC bought the company, unless . . . SAC subsequently *destroyed* those files."[5] Opp. at 5. None of the facts pled supports this conclusion. There is no allegation that the device master records or design history files that failed to meet FDA requirements were created pre-Closing, or that they were not modified post-Closing. Compl. ¶ 42(e).

III. The Court Should Deny Leave to Amend as Futile.

The Harts respectfully request that the Court deny leave to amend as futile. Plaintiffs cannot plead fraud. The statements on which the fraud claim is based are not actionable and are subject to the express disclaimers in the Confidential Memorandum and the SPA. Nor can Plaintiffs plead a breach of contract claim. Not only did Plaintiffs' two pre-closing due diligence reviews and the post-closing audit show that the problems Plaintiffs allege were not present in

[5] The AQSOL Report, on which this allegation is based, states that ADI used records it called "Product Flow Documents" as Device Master Records ("DMRs"). AQSOL Rpt. § IV.I.1, p. 14. DMRs are "design files." *See* Compl. ¶ 42(e). Plaintiffs' suggestion that ADI had no such files, Opp. at 5, is disproved by the documentation on which Plaintiffs rely.

Plaintiffs' objection to the Hart's reference to the AQSOL report is not well-founded. Plaintiffs claim that the AQSOL report is protected by Federal Rule of Evidence 408 because it was provided by Plaintiffs in the context of settlement discussions and also does not constitute the basis of the Plaintiffs' claims. The AQSOL Report is not protected by Rule 408. As Plaintiffs know, the Harts' attorneys received it from the Harts before Plaintiffs sent it. *See* Kortmansky Dec. Exhibits C, D, E. Second, the AQSOL Report is not "[e]vidence of (1) furnishing or offering or promising to furnish or (2) accepting or offering or promising to accept, a valuable consideration in compromising or attempting to compromise a claim[,] . . . [or] [e]vidence of conduct or statements made in compromise negotiations[.]" Fed. R. Evid. 408. The AQSOL Report is evidence that can be submitted at trial. Plaintiffs admit that the AQSOL report provide the basis for their claims. Plaintiffs state that all but three of the problems referenced in the Complaint are found in the AQSOL report. Opp. at 12 n.6.

Plaintiffs' objection to the Harts' inclusion of the Exclusivity Agreement is also baseless. Opp. at 3 n.2. The Exclusivity Agreement grants the due diligence Plaintiffs allege in paragraphs 18-20 and is thus integral to the Complaint. The Exclusivity Agreement is referenced in the letter of intent, *see* LOI at 2, which Plaintiffs incorporate in the Complaint, *see* Compl. ¶ 17.

2009, ADI received ISO 13485 certification on May 16, 2009, *i.e.*, one month after Closing on April 20, 2009.[6] According to the AQSOL Report, the FDA Regulations "and ISO 13485 have . . . very similar" requirements, and the "[t]he issues noted in [the AQSOL Report]" would prevent ADI from receiving ISO 13485 certification. AQSOL Rpt. § V.B.1, p. 17. The May 2009 ISO 13485 certification establishes that the problems AQSOL identified at ADI in May 2010 could not have been present at Closing. Also, Plaintiffs already amended their Complaint once. After receiving the Harts' Motion to Dismiss, Plaintiffs filed an Answer and Counterclaims in No. 12 Civ. 3560, now consolidated with this action. Dkt. No. 9. Paragraphs 45 through 93 of Plaintiffs' Counterclaims repeat the allegations in paragraphs 11 through 59 of their Complaint almost verbatim. Leave to amend should be denied.

CONCLUSION

For the foregoing reasons, Defendants respectfully request that Plaintiffs' Complaint be dismissed in its entirety and leave to amend be denied.

Dated: New York, New York
August 24, 2012

SULLIVAN & WORCESTER LLP

By:/s/Jonathan G. Kortmansky
Franklin B. Velie
Jonathan G Kortmansky
Siobhan Briley
1633 Broadway, 32nd Floor
New York, NY 10019
(212) 660-3000

Attorneys for Defendants Richard Hart and Marie Louise Trudel-Hart

[6] The Harts can provide a copy of the certification to the Court if it requests.